

Structured Product Labeling (SPL) OTC Sub-team Teleconference

Call-in details: Dial **888-557-8511**; Enter Access Code **5222603#**

(Call 202-429-9260 if there are problems accessing the teleconference.)

Monday, March 9, 1:00 pm – 2:00 pm ET

Agenda (as of March 4, 2009 – subject to change)

- I. Welcome and Introductions** 1:00 - 1:05 pm
- II. Next Standing Teleconference:** March 23, 2009 (unless cancelled)
- III. Clarification of from February 23, 2009, Teleconference** 1:05 – 1:25 pm
 - A. PDP/text submission electronic submissions requirements
 - B. June 1, 2009, implementation date
- IV. Development of General SPL Press Release** 1:25 – 1:30 pm
- V. SPL Process Team Membership** 1:30 – 1:35 pm
- VI. Proposed Activities for SPL OTC Sub-team** 1:35 – 1:45 pm
- VII. Upcoming SPL Educational Forums** 1:45 – 1:50 pm
 - A. FDA webinars
 - B. FDA face-to-face meeting on May 21, 2009, (registration is now closed due to space limitations)
 - C. Others???
- VIII. Other** 1:50 – 2:00 pm

MDH/03-04-09

9 March 2009 SPL OTC Sub-team call agenda 030409.doc

Last Revised: March 4, 2009 Sent: March 6, 2009